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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
Office Action Summary	10/748,589	SIMPSON ET AL.
	Examiner	Art Unit
	Kristine K. Rapillo	4137

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>30 December 2003</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-23</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-23</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>06 May 2004</u> is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date <u>8/6/2004; 7/6/2005</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 23 are pending.

Drawings

1.   The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4)

because reference character "4817" has been used to designate both Compare Again

(Figure 40) and Compare (Figure 41).

2.   The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5)

because they do not include the following reference sign(s) mentioned in the

description:

- Figure 1, Reference Numbers: 103 (paragraph [0099]), 109 (paragraph [0099]),

   and 210 (paragraph [0104]).

- Figure 3, Reference Numbers: 116 (paragraph [0093]) and 121 (paragraph

   [0091]).

- Figure 6, Reference Number: 532 (paragraph [0269]).

- Figure 12, Reference Number: 1200 (paragraph [0413]).

- Figures 13 and 14, Reference Numbers: 1350 (paragraph [0420]), 1460

   (paragraph [0420]), and 2350 (paragraph [0419]).

- Figure 43, Reference Numbers: 4810 (paragraph [0403] in the amendment

   dated 5/6/2004] and 4811 (paragraph [0403] in the amendment dated 5/6/2004].

- Figure 55A, Reference Numbers: 5538 (paragraph [0455]), 5540 (paragraph

    [0455]), 5542 (paragraph [0455]), 5544 (paragraph [0455]), and 5546 (paragraph

    [0455]).

- Figure 55B, Reference Numbers: 5572 (paragraph [0462]) and 5574 (paragraph

    [0463]).

3.   The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5)

because they include the following reference character(s) not mentioned in the

description:

- Figure 4, Reference Numbers: 126 and 128

- Figure 6, Reference Numbers: 524 and 526

- Figure 11, Reference Numbers: 1008 (a – f), 1012 (a – c), and 520 (a – e)

- Figure 13, Reference Numbers: 1310 and 1320

- Figure 14, Reference Numbers: 1410, 1430, and 1450

- Figure 15, Reference Number: 1580

- Figure 55B, Reference Numbers: Title of Figure 55B, A, C, D, and E

- Figure 55C, Reference Numbers: Title of Figure 55C, B, C, D, E, 5538, 5542,

    5544, and 5546

- Figure 56, Reference Numbers: 5620, 5622, 5624, and A

- Figure 57A, Reference Numbers: The figure title "57A", A and B

- Figure 57B, Reference Numbers: The figure title "57B", A and B

- Figure 59, Reference Number: 5910

- Figure 61, Reference Number: 6136

4.   The drawings are objected to because the steps illustrated in Figure 52 do not correspond to the procedure discussed in paragraph [0391] in the specification.

5.   The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "1006d" (Figure 11) and "1006e" (paragraph [0329] of the specification) have both been used to designate duration. In addition, reference characters "1006e" (Figure 11) and "1006f" (paragraph [0329] of the specification) have both been used to designate infusion.

Specification

6.   The disclosure is objected to because of the following informalities: The amendment dated 5/6/2004 (page 24) changes the reference numbers found in the specification (paragraph [0474]) from 56XX to 59XX with out any indication of which figure the reference numbers refer to. Appropriate correction is required.

7.   The disclosure is objected to because of the following informalities: The reference numbers used throughout the specification are not associated with the figures to which they reference.

        Appropriate correction is required.

8.   The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

9.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
>   (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10.   Claims 15 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by

Mault (U.S. Publication No. 2001/0044588 A1).

In regard to claim 15, Mault teaches a system for providing messages to remote

clinician devices in a healthcare system, comprising: a request message generated

substantially within a time interval by a program within a software application executed

by a clinician device, and a response message generated by a first computer in

response to the request message (paragraph [0012]).

In regard to claim 21, Mault teaches a system, as per claim 15, wherein the

clinician device is attached to a network within a healthcare facility (paragraph [0037]).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1 – 6, 8 – 13 and 20 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Bar-Gadda et al. (WO 99/42933) in view of Mault.

In regard to claim 1, Bar-Gadda et al. teaches a method of generating a signal

that a notification condition exists for a specific patient (page 3, lines 29 – 31) and

transmitting the signal relating to the notification condition to a first clinician's device

(page 3, lines 31 – 34).

Bar-Gadda et al. fails to teach a method for executing a notification process

within a healthcare system comprising the steps of: indicating the notification condition

on the clinician's device and operating a timer.

Mault teaches a method for executing a notification process within a healthcare

system comprising the steps of: indicating the notification condition on the clinician's

device (paragraph [0043]) and operating a timer (paragraph [0008]).

Therefore, it would have been obvious to a person of ordinary skill in the art at

the time the invention was made to include a method for executing a notification

process within a healthcare system comprising the steps of indicating the notification

condition on the clinician's device and operating a timer, as taught by Mault with the

motivation of communicating the remote monitoring of a patients physiological

parameters by health care providers to a computer system or other nurses/physicians

(paragraph [0035]).

    In regard to claim 2, Bar-Gadda et al. teaches a method, as per claim 1, further

comprising the step of transmitting the signal to a second clinician's device if a response

to the notification condition is not received prior to a predefined timer limit (page 5, lines

17 – 26). Bar-Gadda et al. does not explicitly teach sending a notification to a second

clinicians device, however, if a notification can be sent to a first clinicians device, it is

obvious it can be sent to a second clinicians device.

    Therefore, it would have been obvious to a person of ordinary skill in the art at

the time the invention was made to transmit a signal to a second clinicians device if a

response to the notification condition is not received prior to a predefined timer limit

because the step of transmitting a signal to a second clinicians device does not

patentably distinguish the claimed invention.

In regard to claim 3, Bar-Gadda et al. teaches a method, as per claim 1, further comprising the step of transmitting the signal relating to the notification condition to a charge clinician (page 3, lines 31 – 34). Bar-Gadda et al. discloses a method in which notification can be sent to one or more users, which would include a charge clinician.

In regard to claim 4, Bar-Gadda et al. teaches a method, as per claim 2, wherein the step of transmitting the signal to the second clinician's device is executed when the timer elapses (page 5, lines 17 – 26). Bar-Gadda et al. discloses a method in which a clinician may specify times, i.e. set the timer, before a notification is transmitted.

In regard to claim 5, Bar-Gadda et al. teaches a method, as per claim 1, wherein the step of transmitting the signal relating to the notification condition to the first clinician's device comprises transmitting a wireless notification condition signal to the first clinician's device (page 3, lines 31 – 34) and (page 4, lines 9 – 11).

In regard to claim 6, Bar-Gadda et al. teaches a method, as per claim 1, wherein the step of transmitting the signal relating to the notification condition to the second clinician's device comprises transmitting a wireless notification condition signal to the second clinician's device (page 3, lines 31 – 34) and (page 4, lines 9 – 11).). Bar-Gadda et al. discloses a method in which notification can be sent to one or more users.

In regard to claim 8, Bar-Gadda et al. teaches a method, as per claim 1, wherein there is a many-to-many relationship between first clinicians and charge clinicians (page 5, lines 5 – 7).

In regard to claim 9, Bar-Gadda et al. teaches a method, as per claim 1, wherein the step of transmitting the signal comprises sending the signal to one of a PDA, a mobile phone, a pager, an e-mail address, an instant messaging receiver or a conventional telephone (page 3, lines 24 – 26 and page 4, lines 8 – 11).

In regard to claim 10, Bar-Gadda et al. teaches a method, as per claim 1, wherein the step of transmitting the signal to the first clinician's device comprises sending the signal simultaneously to at least two of a mobile phone, a pager, an e-mail address, an instant messaging receiver or a conventional telephone (page 4, lines 8 – 11).

In regard to claim 11, Bar-Gadda et al. teaches a system for providing messages to remote clinician devices in a healthcare system comprising a request generated by the remote device and received by the first central computer and a response message generated by the first central computer (page 5, lines 34 – 35 through page 6, lines 1 – 7).

Bar-Gadda et al. fails to teach a first central computer attached to a network; a remote device associated with the clinician and operably attached to the network, the

remote device comprising a visual display; and, wherein the response message generated by the first central computer is provided in a humanly readable format on the visual display of the remote device.

Mault teaches a first central computer attached to a network (paragraph [0036]); a remote device associated with the clinician and operably attached to the network, the remote device comprising a visual display (paragraph [0035]); and, wherein the response message generated by the first central computer is provided in a humanly readable format on the visual display of the remote device (paragraph [0043]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to a first central computer attached to a network; a remote device associated with the clinician and operably attached to the network, the remote device comprising a visual display; and, wherein the response message generated by the first central computer is provided in a humanly readable format on the visual display of the remote device as taught by Mault with the motivation of enabling a health care provider remote access to physiological parameters and to alert physicians/nurses of any out of tolerance results from the measurement of the parameters (paragraph [0016]).

In regard to claim 12, Bar-Gadda et al. teaches a system, as per claim 11, further comprising: a second computer attached, via a communication link, to the first central computer at least partially located within a health care facility, wherein the request generated by the remote device is received by the first central computer and the second

central computer, wherein a response message is generated by the second central computer in response to the request generated by the remote device, and wherein the response message generated by the first central computer comprises the response message provided by the second central computer and additional data added by the first central computer (page 4, lines 2 – 7). Bar-Gadda et al. describes a web server computer, as well as an application server computer, which correlate to a first and second computer.

In regard to claim 13, Bar-Gadda et al. teaches a system, as per claim 12, wherein said remote device further comprising a browser responsive to the response message generated by the first central computer (page 7, lines 2 – 4, lines 10 – 14, and table) where e-mail messages can be constructed from a desktop PC or PDA.

In regard to claim 20, Bar-Gadda et al. teaches a system, as per claim 15, wherein the software application is a Web browser (page 7, lines 2 – 4 and table).

13.   Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Gadda et al. and Mault as applied to claims 1 and 16, and further in view of Dempsey et al. (U.S. Patent No. 6,057,758).

In regard to claim 7, Bar-Gadda et al. and Mault teach a method of executing a notification process as per claim 1.

Bar-Gadda et al. and Mault fail to teach a method wherein there is a many-to-many relationship between first clinicians and patients.

Dempsey et al. teaches a method wherein there is a many-to many relationship between first clinicians and patients (column 8, lines 47 – 55).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein there is a many-to many relationship between first clinicians and patients as taught by Dempsey et al. with the motivation of allowing a physician or other health care provider the means of remotely monitoring the health status of patients in their care (column 4, lines 40 – 54).

14.   Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Gadda et al. and Mault and further in view of Eggers et al. (U.S. Publication No. 2002/0169636 A1).

In regard to claim 14, Bar-Gadda et al. and Mault teach a system, as per claim 12.

Bar-Gadda et al. and Mault fail to teach a system wherein the remote device receives a second response message generated by the second central computer in response to a second request generated by the terminal device, wherein the second

response message and the second request are routed through the first central computer.

Eggers et al. teaches a system wherein the remote device receives a second response message generated by the second central computer in response to a second request generated by the terminal device, wherein the second response message and the second request are routed through the first central computer (paragraphs [0031] and [0060]). Eggers discloses a system in which messages (i.e. communication) can occur via the use of bidirectional data sources.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the remote device receives a second response message generated by the second central computer in response to a second request generated by the terminal device, wherein the second response message and the second request are routed through the first central computer as taught Eggers et al. with the motivation of communicating patient information to and from a variety of sources to improve patient care (paragraph [0010]).

15.   Claims 16, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Gadda et al. in view of Eggers et al. (U.S. Publication No. 2002/0169636 A1).

In regard to claim 16, Bar-Gadda et al. and Mault teach a system as per claim 15.

Bar-Gadda et al. and Mault fail to teach a system wherein the response message comprises information contained within a data packet generated by a medical device, and wherein the information is modified in response to a change in the information contained within another data packet generated by the medical device.

Eggers et al. teaches a system wherein the response message comprises information contained within a data packet generated by a medical device, and wherein the information is modified in response to a change in the information contained within another data packet generated by the medical device (paragraph [0036]). The Examiner interprets data packets to be the patients medical record, including patient test results, height, weight, etc.

The motivation for combining the teachings of Bar-Gadda et al., Mault, and Eggers et al. is discussed in the rejection of claim 14.

In regard to claim 17, Bar-Gadda et al. teaches a system, as per claim 16, wherein the program is written in JAVA (page 8, lines 6 – 8).

In regard to claim 22, Bar-Gadda et al. and Mault teach a system as per claim 16.

Bar-Gadda et al. and Mault fail to teach a system wherein the medical device is an infusion pump.

Eggers et al. teaches a system wherein the medical device is an infusion pump (paragraph [0026]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the medical device is an infusion pump as taught by Eggers et al. with the motivation of providing a system in which a medical device can be programmed to deliver medication to a patient (paragraph [0011]).

16.   Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Gadda et al. in view of Eggers et al. and further in view of Dempsey et al.

In regard to claim 18, Bar-Gadda et al., Mault, and Eggers et al. teach a method of executing a notification process as per claim 16.

Bar-Gadda et al., Mault, and Eggers et al. fail to teach a system wherein the program is written in C#.

Dempsey et al. teaches a system wherein the program is written in C# (column 10, lines 38 – 45). C# is also known as C-Sharp. Dempsey et al. discloses an object oriented programming language of which C-Sharp (or C#) is included.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system where the program is written in C# as taught by Dempsey et al. with the motivation of providing a software program which provides an interface with the handheld terminals such as a PDA (column 9, lines 31-32).

17.   Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-

Gadda et al., Mault, and Eggers et al. as applied to claim 16 above, and further in view

of www.catharsismedical.com (12/9/01).

         In regard to claim 19, Bar-Gadda et al., Mault, and Eggers et al. teach the system

of claim 16.

         Bar-Gadda et al., Mault, and Eggers et al. fail to teach a system wherein the

program is written in Visual Basic Script.

         www.catharsismedical.com teaches a system wherein the program is written in

Visual Basic Script (paragraph 6). www.catharsismedical.com uses Windows NT which

is a Visual Basic Script.

         Therefore, it would have been obvious to a person of ordinary skill in the art at

the time the invention was made to include a system wherein the program is written in

Visual Basic Script as taught by www.catharsismedical.com with the motivation of

allowing the infusion pump and hardware to send messages to a Windows NT server

(paragraph 17).

18.   Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-

Gadda et al. in view of Eggers et al. and further in view of Paula ("MEMS Sensors

Branch Out". Mechanical Engineering. New York: Oct 1996. Vol. 118, Iss. 10; pg 64).

In regard to claim 23, Bar-Gadda et al., Mault, and Eggers et al. teach the system

of claim 16.

Bar-Gadda et al., Mault, and Eggers et al. fail to teach a system wherein the

medical device is a MEMS device.

Greg teaches a system wherein the medical device is a MEMS device

(paragraph 7).

Therefore, it would have been obvious to a person of ordinary skill in the art at

the time the invention was made to include a system wherein the medical device is a

MEMS device as taught by by Greg with the motivation of offering a smaller size, lower

cost, and more accurate medical device (paragraph 42).

Conclusion

19.   The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

- Stutman et al. (U.S. Patent No. 5,416,695) discloses a medical alert system,

  which enables a health care provider to monitor patients remotely based on pre-

  set parameters.

- Shankar et al. (U.S. Publication Number 2003/0083719 A1) discloses an

  implantable cardiac therapy device, which is in communication with other

  devices. The medical device can be communicated to over a network, using

  PDA's and mainframe computers.

- "Sensors in Medicine." Charles B. Wilson. Western Journal of Medicine. San Francisco: Nov/Dec 1999. Vol. 171, Iss. 5/6; pg. 322. Wilson discloses the use of microelectro-mechanical systems with medical devices.

20.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristine K. Rapillo whose telephone number is 571-270-3325. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Akm Ullah can be reached on 571-272-2361. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

AKM ULLAH
SUPERVISORY PATENT EXAMINER